

REMARKS

Claims 1-51 are pending in the application.

Restriction Requirement

Claims 1-51 stand subject to a Restriction Requirement according to which the Examiner has divided the claims into twelve groups.

In response to the Restriction Requirement, applicant previously elected the claims of Group I, i.e., claims 1-5, for continued prosecution in the application.

Claims Rejections - 35 U.S.C. §§ 102 and 103

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,536,267 to Edwards et al. ("Edwards").

Claims 1-5 stand also rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,304,120 to Crandell et al. ("Crandell").

Applicant respectfully traverses the rejection of claim 1 as anticipated by Crandell. Applicant's invention is directed to a medical instrument including a plurality of hollow *needle* elements. The instrument of Crandell does not include needle elements and one of ordinary skill in the art would not consider providing the instrument of Crandell with needle elements, given the purpose and use of the Crandell instrument. Crandell is directed to a catheter device inserted into a blood vessel for treating endothelial cells along the inner wall of the vessel. The catheter device includes a plurality of circumferentially spaced injection tubes (16) that deliver a fluid medium carrying preselected macromolecules into the blood vessel. The device further includes electrodes for generating short pulses of high intensity electric fields to make the endothelial cells on the inner wall of the blood vessel transiently permeable to permit the

macromolecules to enter the endothelial cells without killing them. Crandell does not teach the use of needles, but instead teaches the use of electrical current to move a macromolecular payload into endothelial cells of a patient. Providing needles would be useless if not dangerous in the context of the Crandell methodology.

In response to the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Edwards, applicant has amended claim 1 herein to provide a better definition of the invention. Applicant respectfully maintains that amended claim 1 distinguishes the invention over the prior art and particularly over the art relied on by the Examiner in rejecting the claims of the instant application.

Per amended claim 1, applicant's invention is directed to an endoscopic medical instrument comprising an elongate member and a plurality of hollow needle elements connected to one end of the elongate member. The elongate member is sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope. The needle elements extend in a direction away from the one end of the elongate member and are each convex on an outer side facing away from others of the needle elements and concave on an inner side facing the others of the needle elements so that the needle elements together define a bulbous ovoid shape, with tips of the needle elements angled inwardly at a distal tip of the medical instrument. The needle elements are each sufficiently flexible to negotiate bends in the biopsy channel of the endoscope.

Applicant's invention finds particular application in the diagnosis and treatment of colon cancer, the second most fatal disease. Applicant's invention will obviate a serious complication of conventional procedures for the removal of colon polyps, that is,

the perforation of the colon in attempts to sectionally ablate the polyps using a cauterization loop or snare. Applicant's device will save lives.

The Edwards reference is directed a laparoscopic electrode ablation apparatus. It is clear from the drawings and from the associated medical procedure described in the specification that the Edwards device is a device for use with a rigid cannula or catheter (12), wherein a distal end portion of the cannula or catheter is inserted percutaneously into a patient with the assistance of a trocar or obturator (30). The cannula or rigid catheter (12) has a short shaft (see Fig. 1 showing length of catheter relative to a handle).

In contrast, applicant's device is designed for flexibly endoscopy. Applicant's device includes an elongate needle-holding member is sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope. Such a biopsy channel is long (up to several feet long) and narrow (several millimeters wide) and is bendable through radii of curvature that prohibit the passage of rigid instrument parts (such as needles) that are longer than one centimeter.

Nothing in the Edwards disclosure teaches a flexible endoscopic instrument. Nothing in the Edwards teachings would motivate one of ordinary skill in the art to provide an instrument with an elongate needle-holding member that is sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

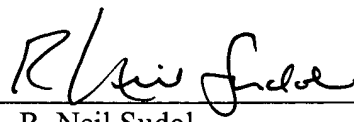
Conclusion

For the foregoing reasons, independent claim 1, as well as claims 2-5 dependent therefrom, is deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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